

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference H 1694 PCT S3		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/07069	International filing date (day/month/year) 02.07.2003	Priority date (day/month/year) 02.07.2002
International Patent Classification (IPC) or both national classification and IPC C07K14.00		
Applicant GENOVA, LTD.		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 6 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

 These annexes consist of a total of sheets.

- This report contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the International application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 02.02.2004	Date of completion of this report 05.11.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office - Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840	Authorized Officer Panzica, G Telephone No. +49 30 25901-328 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/EP 03/07069**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-77 as originally filed

Sequence listings part of the description, Pages

1-22 as originally filed

Claims, Numbers

1-10 as originally filed

Drawings, Figures

1-3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.
☒ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

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International application No. PCT/EP 03/07069

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 1-10 (partly)

because:

☒ the said international application, or the said claims Nos. 7-9 (method of treatment) relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 1-10 (partly)

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	2, 4-10
	No: Claims	1, 3
Inventive step (IS)	Yes: Claims	-
	No: Claims	1-10
Industrial applicability (IA)	Yes: Claims	1-10
	No: Claims	-

2. Citations and explanations

**INTERNATIONAL PRELIMINARY
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see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: MOREN ANITA ET AL: "Identification and characterization of LTBP-2, a novel latent transforming growth factor-beta-binding protein" JOURNAL OF BIOLOGICAL CHEMISTRY, vol. 269, no. 51, 1994, pages 32469-32478, ISSN: 0021-9258

D2: BASHIR MUHAMMAD M ET AL: "Analysis of the human gene encoding latent transforming growth factor-beta-binding protein-2" INTERNATIONAL JOURNAL OF BIOCHEMISTRY AND CELL BIOLOGY, vol. 28, no. 5, 1996, pages 531-542, ISSN: 1357-2725

Examination has been carried out limitedly to invention no.1 as set in the International Search Report, i.e. relatively to Sequence No.3 of the sequence listing.

1. Lack of novelty (Art. 33.2 PCT).

- 1.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1 and 3 is not new in the sense of Article 33(2) PCT.
- 1.2 The documents D1 (see fig.2) and D2 (see fig. 1 and fig.2) disclose sequences with 100% identity with claimed sequence 3 of the sequence listing. Further, in D1 expression of the cloned sequence is also disclosed (see Abstract and Results).
- 1.3 Note that the term "comprising" extends the scope of the claims to any longer polypeptide.

2. Lack of inventive step (Art.33.3 PCT).

- 2.1 In principle, all claims lack of inventive step because their embodiments can be directly inferred by the polypeptides of D1 without any inventive step. Therefore claims do not meet the criteria of inventive step, to the senses of Article 33(3) PCT. The technical features of claim 2, fusing peptides of claim 1 with a heterologous polypeptide sequence, as far as no special sequence to be fused is

specified, are directly derivable from the standard procedures in the state of the art.

- 2.2 On the same basis, lack of inventive step is to be recognized for the production of a composition including a carrier or a diluent is also directly derivable from the standard general knowledge. Similarly for the administration by injection of the composition.

3. Lack of disclosure and lack of support (Arts. 5 and 6 PCT).

- 3.1 Concerning subject matter of claims 4, 5, 7 and 10, the present application does not provide support to the senses of Art. 5 PCT. Regarding claim 4, no antibody able to bind specifically the polypeptide of sequence No.3 has been disclosed by the present application. Similarly for the method of identifying said antibody, in claim 5, which therefore remains a problem still to be solved.
- 3.2 The method referred to in claim 7, is also unsupported by the present application, since the application neither proves nor confirms any biological function, by means of experimental data, that could support the claimed method.
- 3.3 In view of the above arguments, also claim 10 remains unsupported, because until a function or more functions for the given sequence has been disclosed, no modulation of any function can be performed and verified.

4. Further considerations.

- 4.1 Concerning the national/regional phase: subject-matter of claims 7 - 9 (method of treatment to be performed on human or animal body) is not patentable (see e.g. Art.52.4 EPC).
- 4.2 D1 is not acknowledged in the application as relevant prior art, as requested to the senses pf Rule 5 PCT

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